MICHIGAN ENVIRONMENTAL SCIENCE BOARD

COUNCIL OF GREAT LAKES GOVERNORS SPECIAL FISH ADVISORY PANEL
MEETING SUMMARY
FRIDAY, OCTOBER 28, 1994
SHERATON LANSING HOTEL
LANSING, MICHIGAN

PANEL MEMBERS PRESENT
Dr. Lawrence Fischer, Chair
Dr. Gary Carlson
Dr. Joseph Jacobson
Dr. Barbara Knuth
Dr. Martha Radike
Dr. Peter Thomas
Dr. Kendall Wallace
Mr. Keith Harrison, MESB Executive Director

PANEL MEMBERS ABSENT
Dr. Michael Bolger
Dr. Mark Roberts

DMB/EAD SUPPORT STAFF PRESENT
Mr. Jesse Harrold, Environmental Officer
Ms. Patricia Hiner, Secretary

I CALL TO ORDER

Dr. Lawrence Fischer, Chair, called the meeting of the Special Fish Advisory Panel to order at 9:00 a.m. Dr. Fischer introduced the Panel members and stated the charge given to the Panel via the Michigan Environmental Science Board (MESB) by the Council of Great Lakes Governors (see Attachment 1). He indicated that the Panel will operate in the same manner as the MESB. Its review of the September, 1993 *Protocol for a Uniform Great Lakes Sports Fish Consumption Advisory* (Protocol) will focus on the adequacy of the science used to develop it. Policy matters relating to the Protocol will not be issues of concern for the Panel's consideration. The Panel will operate by consensus and Panel members will be responsible for preparing their assigned portion of any final report. Final report editing will be a joint effort by all Panel members.

II EXECUTIVE DIRECTORS REPORT

Mr. Harrison, MESB Executive Director, briefly discussed the general procedures which are used by MESB and which will be used by the Panel during the course of its investigation for expense reimbursement, meeting summaries, document distribution and final report preparation.

III PRESENTATION

Mr. John Hesse, Michigan Department of Public Health (MDPH), presented an overview of the process used by the Great Lakes Sport Fish Advisory Task Force (Task Force) to develop the Protocol. A summary of his presentation is contained in Attachment 2.

Dr. Carlson asked if any changes had been made to the Protocol as a result of the two sets of solicited and one set of unsolicited review comments. Mr. Hesse indicated that discussions have taken place among the Task Force members but no changes had been made to the document at this time.

Dr. Fischer asked how many states were currently using the Protocol. Mr. Hesse stated that Minnesota and Ohio have begun to use the Protocol. Ohio modified one of the numbers slightly due to political considerations.

IV PANEL DISCUSSION

Scientific Basis for Proposed Protocol

NOAELS and LOAELS Selection. Dr. Wallace indicated that he was not convinced that PCBs should be the driving substance in determining the fish advisory. Dr. Thomas concurred on the grounds that PCB levels in the Great Lakes have been dropping. Dr. Fischer added that in Michigan dioxins and mercury are prominent contaminants in some waters and questioned how such data would be handled by the Protocol. Mr. Hesse replied that if dioxins or mercury, or any other contaminant was to become the common major toxicant in the Great Lakes, it would also become the driving contaminant for the Protocol. In terms of human exposure to all the other organic contaminants found in Great Lakes fish, the Task Force members felt that PCBs served as a good indicator. The only places, currently, where mercury could drive a health advisory would be in Lake St. Clair and in some inland lakes.

Dr. Milton Clark, U.S. Environmental Protection Agency (USEPA), stated that 85% to 90% of the cancer risk in the Great Lakes fishes is attributable to PCBs and there is a direct relationship between the amount of PCBs and dibenzofurans. PCB is an excellent chemical to use as a surrogate. It is consistent with the USEPA that the cancer risk factor be referred to as a health protection factor.

Dr. Fischer commented that it appeared that the USEPA was looking for a reference dose approach to drive the advisory despite the fact that the Protocol does not use reference doses. Dr. Clark indicated that the Protocol is taking a reference dose approach and labeling it as a health protection value considering cancer. The USEPA does not have a problem with this particular approach because the Task Force was able to add in the cancer risk. In addition, there are communication instruments which are being looked at by the Task Force which will handle the cancer risk part.

Dr, Fischer summarized this portion of the discussion by stating that it was unclear how other pollutants could drive the fish advisory under the current Protocol.

Assumptions Used to Calculate Exposure. Dr. Fischer commented that the Protocol states that an expert committee approach was used to reach a decision on the health protection value (HPV) and that the Task Force did not develop and utilize a quantitative method to weigh specific studies. Apparently, all studies showing effects of PCBs were given equal weight.

Dr. Carlson indicated that it appears that the HPV was based on the Michigan (Jacobson *et al*.) and North Carolina (Rogan) studies, but it is unclear from reading the text of the Protocol. Dr. Fischer added that the number which the Task Force finally came up with was the Minnesota number. The premise behind the calculation of that number is Dr. Jacobson's data. Dr. Jacobson concurred and indicated that it appeared that the Task Force took the Tilson analysis and modified it by changing one of the assumptions.

Dr. Fischer asked Dr. Jacobson how comfortable he was with his study and findings. Dr. Jacobson took the position that methodologically his study was sound and that criticisms, which have focused on supposed failure to control for such confounders as alcohol and smoking, are unfounded. Nevertheless, he expressed some discomfort about the degree to which the Protocol appears to rely on the Michigan study data for two reasons: (1) there has been as yet no opportunity to replicate his findings (and, given the decline in environmental PCB levels, it may be difficult to find a comparably exposed cohort for a replication study); and (2) the long-term functional significance of his findings has not been determined yet.

Dr. Jacobson stated, however, that he recognized that public health considerations make it necessary to set standards before additional data are collected. Because the Michigan study has provided the most extensive data to date on the effects of background level exposure on the fetus, it seems appropriate to give these data considerable weight in determining recommendations for women of child-bearing age. On the other hand, the relevance of the Michigan data for males and older women is questionable, given the consistent evidence that the fetus is substantially more vulnerable to these contaminants. The Protocol distinguishes between child-bearing age women and others in recommending that the former limit their intake per occasion. However, it appears to use the Michigan data to determine the total intake that would be considered safe for any individual, even though those data bear only on prenatal exposure. Given the potential nutritional benefits of fish consumption, it would not seem advisable to recommend limiting intake to the levels found harmful to the fetus for the nonchild-bearing sectors of the population.

In the Michigan data, there were moderate correlations between Lake Michigan fish consumptions and PCB levels in mothers' blood and breast milk. There was also a moderate correlation between the mothers' body burdens and the cord serum PCB levels. The latter correlation was probably understated in the data due to the limitations

in the packed column gas chromatography analysis, which was state-of-the-art at the time. There was no direct correlation between maternal fish consumption and cord serum PCB level. In other words, fish predicted what the mother got and the mother's level predicted what the baby got, but there was no direct correlation from fish to baby, again presumably due to limitations in the reliability of the cord serum analyses. It should be noted also that fish consumption was only one of a range of sources of PCB exposures to which this population was (and most contemporary populations are) exposed. Although some have suggested that methylmercury exposure, which was not measured prenatally in the Michigan study, may have been a confounding influence in these data, the levels of methylmercury in Lake Michigan fish were believed to be very low at the time.

Sensitivity Analysis. Dr. Carlson expressed a need for the Panel to be cognizant of the pharmacokinetics of all PCBs and the inadequacies of the data presented on page 44 of the Protocol. He added that Scandinavian fish and seal data on PCB isomer exposures would be useful to the Panel's investigation.

Dr. Fischer asked if there was any scientific consensus on whether the mixture of congeners in fish represented a potentially more harmful group of compounds. He continued by stating that to his knowledge, toxic equivalents for PCBs were not being used at this time because the consensus is that they are not satisfactory. Dr. Carlson added that he was not certain how many studies have been done on the effects of PCBs and individual isomers on such concerns as reproduction and neurobehavior.

Dr. Carlson added that a publication by Brown is scheduled to be released within the month which should provide the Panel with new toxicological information on 209 PCBs and the parent compound. Dr. Clark also suggested that a review of several pertinent papers on the subject would be useful to the Panel's discussion. Dr. Clark indicated that he will provide the Panel with the papers.

Dr. Fischer summarized this portion of the discussion by stating that there appears to be no general criticism by the Panel of the sensitivity analysis used in the Protocol. However, such an analysis does not constitute a validation of the number.

Exposure Calculation. Dr. Fischer indicated that upon his review of the exposure calculation used in the Protocol, 50% of the contamination could be avoided if proper food preparation procedures were followed. He indicated that he also wanted to know if Minnesota's value of 4.12 _g/g was for whole fish or trimmed fish. Mr. Hesse indicated that Task Force member Dr. Pam Shubat could better address that question.

Dr. Knuth commented that depending on the type of angler, anywhere from 30% to 80% follow the recommended fish trimming procedures. Some anglers and some ethnic groups may have more of a tendency to not use the trimming procedures and to consume the fat and skin.

Dr. Wallace indicated because of the extended biological elimination time of PCBs, it might be more reasonable for the Protocol to indicate 12 meals of Great Lake fish a year rather than one meal a month. He also pointed out that there was evidence that proper fish preparation could remove up to 80% of the contamination in some cases.

Dr. Carlson expressed concern with how the Protocol (pages 64-66) categorizes fish into different consumption groups based on limitations of the analytical method such that all fish that have no detectable PCBs are given a value of 0.05 ppm. As a result, one positive fish in a group could move that particular fish species/size into Group 2. He suggested that this should be looked at by the Panel.

Risk Communication

Dr. Knuth provided a critique on information dissemination on the fish consumption warnings. She first established that the standardization between states on the benefits and risk of fish consumption, fish preparation methods and categorization of different fishes are all reasonable. The use of simple statements with implied qualifications may not be effective in moderating fish consumption. Each fish-consuming social group must be given special treatment in order to communicate the desired message. This targeting effort may involve as many different preparations per state as there are audiences. It cannot be assumed that communication methodology used in one state will be applicable in another, although communication needs of similar audiences will likely also be similar. Other considerations include what is being published in what publication, whether the distribution of information is being done in a timely manner, and whether the states are coordinating their presentations to impact at the same time. There are several communication gaps in the proposed warning; one is seemingly focusing only on a special segment of society (women of child-bearing age and children) and ignoring men and women beyond child-bearing age; another is providing the answer to: "if I don't do it, what is the consequence?"

Dr. Jacobson questioned if long term exposure to a low dose of PCBs is more traumatic to the fetus than one strong dose with no background. He added that it is difficult to raise the mother's PCB blood level to any degree, with a few meals of fish. Based on his experience, long term accumulation of PCBs in mothers is the significant factor in fetal harm. Mr. Hesse cited a 1983 Michigan experiment conducted on 16 volunteer state employees in which blood levels of PCBs rose from, for instance, from 40 ppm to 80 ppm in a fish eater in a six hour period, and from 5 ppm to 40 ppm in non-fish eaters in six hours. Within 24 hours the levels began decreasing. So there was, initially, rapid uptake to the blood, followed by a decline, but continued accumulation in tissues. Based on what is known about other teratogens, it is appropriate that the advisory contain information on safe frequency of consumption as well as total consumption, for women of child-bearing age and children. In the case of cancer, total body burden of PCBs over time may be more important than temporary peaks.

Dr. Knuth discussed the table on page 20 of the Protocol, saying that it was cumbersome and its interpretation depends on mathematical knowledge that may be

beyond much of the population. She suggested that all labels be in words, leaving off symbols, and that there be two columns for each category. The column for women of child-bearing age and children could state the advice as "one meal a month," emphasizing the importance of frequency and timing in avoiding rapid increased in blood levels for them, while the column for others could be labeled "twelve meals a year," to emphasize total consumption. Dr. Fischer suggested that in addition to the emphasis on the most vulnerable population, there be more emphasis on the positive aspects of fish consumption.

Dr. Fischer pointed out that there are two questions to deal with. The first is deciding which information needs to be communicated; the second, how to tailor the communication to various receptor audiences. Discussion continued about the function of the proposed Protocol for a uniform consumption Advisory - whether it was intended to be used as is or be tailored to specific audiences by the states - and alternatives for construction and distribution of advisories. Dr. Knuth reported that there was strong evidence that 80% to 95% of licensed anglers in the Great Lakes region are aware of advisories and that 60% to 80% of those can remember specifics of the advisories. Dr. Fischer reported that in Michigan, only about 50% of licensed anglers even read the advisories. In Michigan, most anglers get their information from the media. It was also noted that the model advisory contains a guide for women of child-bearing age which mentions exposures to other contaminants, and discusses contaminants in commercial fish.

V PUBLIC COMMENTS AND QUESTIONS

Bob Sills, Michigan Department of Natural Resources, requested that the Panel review the Aroclor 1254 1989 - 1993 studies involving Rhesus monkeys. The studies are critical for two reasons; first, according to some USEPA data, Aroclor 1254 seems to best resemble environmental PCBs in the Great Lakes. Second, the critical effects were not reproductive or environmental, but rather, immune system toxicity, and some ocular and dermal effects that are probably relevant to humans. The data were not available to the Task Force until late in its deliberations, so were not taken into account as much as it should have been in setting consumption limits. Mr. Harrison said that his office would obtain the available data.

Tim Eder, National Wildlife Federation, urged the Panel to move forward with the Protocol. The Federation views the Protocol as a significant step forward in providing much better advice to anglers in the Great Lakes region than they are currently getting. People are not currently receiving adequate advice to protect their health, particularly women of child-bearing age. The Federation is also concerned about the focus on PCBs, when there are other chemicals in the Great Lakes that have the same health effects. In addition, there seems to be no method available to take into account combinations of chemicals. Mr. Eder urged the Panel to encourage states to go ahead with preparing the risk communication package during these proceedings. He was especially concerned about the Lake Erie walleye fishery, about which Michigan anglers

have no advisory. Dr. Fischer responded that until the Panel has evaluated the science that generated the Protocol, such a decision could not be made.

Mr. Bill Kovalak, Detroit Edison, expressed concern about sensitivity analyses, size limits, and lake-wide recommendations in communications. Instead of asking whether the recommended levels are appropriate for sensitive groups, the Panel should be asking how the recommendations were derived. If they are based on average values, they may be overstated, since most fish are on the low side in terms of contamination. Mr. Kovalak also recommended that the risk communication aspect of the advisory be simplified.

Dr. Clark expressed his agency's appreciation for the Panel's work. The USEPA would like the Panel to invite Dr. John Cicmanec from the Office of Research Development, USEPA, to talk about the Rhesus monkey studies, and to review with the Panel other related research, which the USEPA believes will support the 0.05 _g/kg body weight per day value used in the Protocol. He also suggested that Dr. Pam Shubat be invited to attend to answer questions about her pharmokinetic-based paper. He said that the USEPA has completed extensive evaluations on some of the noncancer and cancer properties on Great Lakes fish, and about 85% of the risk is dependent on PCBs. The addition of other chemicals found in the waters does not add significantly to the risk. He will provide the Panel with a paper on derivation of fish advisories using additive types of reference dose approaches. Dr. Clark emphasized that the Task Force has been working on the fish advisory project for eight to nine years and he expressed confidence in its work. He hoped the Panel would fine tune the Protocol.

Dr. Fischer pointed out that the role of the Panel was not to prepare the final advisory or to fine tune the proposed Protocol, but rather to evaluate the science behind it.

VI NEXT MEETING DATE

Mr. Harrison indicated that the next meeting will take place in Lansing on Wednesday, November 30, 1994. An agenda will sent to the Panel members and any other individuals who desire to be placed onto the mailing list for this investigation. Tentative dates for subsequent meetings of the Panel include December 21, 1994 and January 19, 1995.

VII ADJOURNMENT

The meeting was adjourned at 4:15 p.m.

Keith G. Harrison, M.A., R.S., Cert. Ecol.
Executive Director
Michigan Environmental Science Board

ATTACHMENT 2. Presentation by Mr. John Hesse, Michigan Department of Public Health, to the Special Fish Advisory Panel.

Mr. John Hesse, MDPH, stated that he has been involved with efforts to attain uniform fish consumption advisories in the Great Lakes since the early 1980's. He indicated that prior to 1985, each of the four states bordering Lake Michigan had a different advisory for Lake Michigan fish consumption. From 1983 to 1985, the various Lake Michigan jurisdictions reached agreement on a common advisory approach and pooled their data to generate a single advisory for Lake Michigan. To provide added protection for anglers (who tend to eat more fish than the general population) and for sensitive populations, the Lake Michigan Task Force members decided that if 11% of fish samples for a species exceeded U.S. Food and Drug Administration (USFDA) Action Levels, an advisory would be issued that women of child-bearing age and children should not consume that species/or size range and that the general public should not eat more than 1 meal per week. When 50% of the samples exceed an Action Level, the advisory would recommend "no consumption" by anyone. For comparison purposes, if a composite sample of fish in the market exceeded an Action Level, the USFDA would remove the fish from the market and but would not issue any advisory if the Action Level was not exceeded.

With the success of the Lake Michigan states in reaching a common advisory in 1985, the Governors of the Great Lakes states signed the Great Lakes Toxic Substance Control Agreement of 1986 which mandated, among other things, that common fish consumption advisories be developed for each of the Great Lakes. Two years later, the Ontario Ministry of the Environment also signed the agreement but the language was modified that their fish advisories would be "compatible" with those of the states.

In response to the Governors' mandate, the Lake Michigan Task Force was broadened to become the Great Lakes Fish Consumption Advisory Task Force. This new Task Force had representation from 22 state and federal agencies, including the USEPA, USFDA and the Canadian Food and Drug Directorate. The Task Force felt it important to include the federal agencies because of the confusion caused by the large difference between the USEPA's fish consumption risk estimates developed for hazardous waste/discharge regulations versus the USFDA's Action Levels developed for regulation of fish in the market place.

The USFDA Action Levels are no longer considered appropriate for use as trigger levels for advisories to sport anglers for the following reasons: (1) sport anglers tend to eat more fish (average of 15-20 gms/day) than the general population who only obtain fish from the market and restaurants (average of 6.5 gm/day), (2) anglers tend to consume fish caught from only a few locations, while fish from the market are from a large variety of sources, and (3) USFDA Action Levels are not always health-based and must consider economic impacts.

The Task Force decided to use a modified Delphi technique toward generating ideas for a common fish consumption advisory approach and for reaching consensus on one to

be adopted. As a first step, 19 ideas were generated by the Task Force for evaluation. The goal was to reach consensus on a single approach or combination of approaches to later be fleshed out into a detailed protocol. The Task Force discussed these in light of various scientific, social, administrative and legal considerations. First and foremost was that the protocol be scientifically defensible.

While the Task Force met the spirit of the Governors' mandate by having generally uniform advisories by 1987, reaching consensus on a common protocol was much slower. Concurrently, the USEPA proposed a national guidance manual for fish consumption advisories in the fall of 1987. The Task Force supported having uniform procedures nationally but were not in total agreement with the very conservative risk assessment procedures proposed by the USEPA. The Task Force felt the need to achieve a balance between the known health benefits of fish consumption versus protection from potential health threats of trace contaminants.

In 1989, the National Wildlife Federation issued its own version of a fish consumption advisory for Lake Michigan as a demonstration project utilizing USEPA's cancer risk assessment procedures. The state agencies did not support this action and it caused additional public confusion.

In 1990, the Task Force reached consensus to develop a protocol focusing primarily on non-cancer risks with special emphasis on protection against adverse reproductive outcomes. The cancer risk would also be recognized for the general population but in more general terms due to the high uncertainty associated with cancer risk estimates. The draft approach was presented by the Task Force chairperson at the 1990 Annual Meeting of the American Fisheries Society and continued to be refined over the next 3 years. The Protocol received a peer review by several noted national PCB experts during the summer of 1993 and was presented to the Council of Great Lakes Governors in September, 1993 for its consideration. During the following months, the Council coordinated a peer review by four additional experts. Recognizing that a larger regional peer review was still planned, the Task Force decided to consider the combined comments from all reviews prior to making significant revisions. No consistent pattern of comments were received nor were new issues raised which had not been considered by the Task Force in its deliberations.

During the past 15 years, PCB levels in fish from the Great Lakes have decreased significantly. Some species which previously fell into a "no consumption" advisory category would no longer require a "no consumption" advisory even using the most restrictive advisory criteria proposed in the new protocol. The new protocol, however, would establish additional advisory categories in addition to the 1 meal per week advice currently being issued by many of the jurisdictions.

Meanwhile, the USEPA has proceeded with formalization of a 4-volume set of guidance manuals for issuance of fish consumption advisories. Volume 1 (Sampling and Analysis) and Volume II (Risk Assessment) have been released in final form. Volume III (Risk Management) and Volume IV (Risk Communication) are still in draft form.